Section 13

FEB 2 1 2014

510(k) Summary

Submitter:
Maxx Orthopedics, Inc.
531 Plymouth Rd #526
Plymouth Meeting, PA 19462

Date of Revised Summary: February 21, 2014

Establishment Registration Number: 3007311878

Contact:
Nach Dave
Regulatory Consultant
Phone: 732-718-1385
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Device Information:

Proprietary Name:	Freedom® PCK Components
Common/Usual Name:	PCK Components
Classification Name:	Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulation Number:	21CFR 888.3560
Regulatory Class:	Class II
Product Code:	JWH

Identification of Predicate Device:

The Freedom® PCK Components are similar to the following commercially available devices in regards to the fundamental scientific technology, material composition and intended use:

Device Name	Device Class	Product Code	Regulation Number	510(k) number
Freedom® Total Knee system	II	JWH	21 CFR § 888.3560	K082019, K090411
Freedom® Stemmed Tibial Components	II	JWH	21 CFR § 888.3560	K111785

Device Description:

The Freedom® PCK Components is a progressive constraint cemented prosthesis system. The PCK Components consists of CoCrMo composed Stemmed Femoral Component, UHMWPE composed Tibial Liner and Ti-6Al-4V composed Posterior and Distal Femoral Augments. The components are a modification of the previously cleared Freedom® Stemmed Tibial Components (tibial augment) and Freedom® Total Knee System (PS femoral component and PS tibial liner). Also, the Freedom® PCK Components are intended for use with the Freedom® Stemmed Tibial Components and as a part of the Freedom® Total Knee System for total knee replacement (TKR) surgery. The Components will be prescription products consisting of single use only, implantable devices for implanting into patients in an operating theatre by a qualified surgeon.

The devices are to be packaged and terminally sterilized by gamma radiation or ethylene oxide. The packaging is to keep devices sterilized for 5 years. The packaging will be able to be opened easily in an operating theatre without instruments and in a manner that allows the implant to remain sterile.

Intended Use:

The Freedom® PCK Components are designed to be used with the Freedom® Stemmed Tibial Components and as a part of the Freedom® Total Knee System, and is indicated for the following:

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, and/or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods
- Revision surgery where sufficient bone stock and soft tissue integrity are present

The Freedom® PCK Components are intended for cemented use only. The optional Freedom Stemmed Tibial Augments are intended for screw attachment to the Stemmed Tibial Base Plate. This device is for single use only.

Substantial Equivalence for Technological Characteristics:

The proposed Maxx Orthopedics' Freedom® PCK Components and the predicate devices are identical in that they consist of same fundamental scientific technology, device's operating mechanism, material of composition, and intended use.

Both the proposed Freedom® PCK Components and the predicate devices have been designed to mimic the normal knee geometry. Both the proposed and predicate devices are compatible with left and right configurations and available in a variety of sizes that are intended to mimic normal human anatomy. Both the proposed and predicate devices are made of biocompatible materials and are similar in technical design and materials. Components have the same connection mechanisms, For eg, liner tab locks, augment screws, tapers, etc.

Performance Testing:

Summary of Non-Clinical Tests performed on the Freedom PCK Components

Summary of Performance Testing for Freedom® PCK Components

Test Name	Objective
Static and Dynamic Properties of the Freedom PCK Tibial Post	This study evaluates the tibial post fatigue for the Freedom PCK tibial insert during positions of functional gait. The parameters evaluated include a device's static mechanical strength, stiffness, yield, displacement, and dynamic durability.
Stability Characteristics of the Freedom PCK Components	This study evaluates the intrinsic stability of the Freedom PCK Components.
Stability characteristics of the Freedom PCK Components at high flexion	This study evaluates the intrinsic posterior stability of the Freedom PCK Components at high flexion.
Modular Disassembly Characteristics of the Freedom PCK Tibial Insert	This study evaluates the resistance to tibial insert disassembly of the Freedom PCK Components.
Determination of the Range of Motion (ROM) of the Freedom PCK Components	This study evaluates the tibiofemoral ROM of the Freedom PCK Components.

Clinical Testing:

Clinical Testing was not required for these components to support substantial equivalence determination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Maxx Orthopedics, Incorporated
Mr. Nach Dave
Regulatory Consultant
531 Plymouth Road, Suite 526
Plymouth Meeting, Pennsylvania 19462

Re: K131481
Trade/Device Name: Freedom® PCK Components
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: November 22, 2013
Received: November 25, 2013

Dear Mr. Dave:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: Freedom® PCK Components

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices